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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/097,023	06/12/1998	JILL MCFADDEN	290252021800	2472

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EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/08/2003

37

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/097,023

Applicant(s)

MCFADDEN ET AL.

Examiner

Michael J Hayes

Art Unit

3763

JW

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-22, 24-42, 44-48, 50-56, 58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-22, 24-42, 44-48, 50-56, 58 and 59 is/are rejected.
- 7) ☒ Claim(s) 51 and 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the coil between the inner liner and outer cover as recited in claim 52 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53, 54, 55, 56, 58, and 59 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 05-220225 in view of SAMSON (U. S. Patent No. 5,702,373). JP 05-220225 shows a knitted reinforcing metal member 35 with an inner liner and outer cover. Samson is relied upon for description of the JP 05-220225 document. A full translation of JP 05-220225 is not available at this time, but has been requested.

Claims 1-5, 13, 14, 18, 19, 20, 24-27, 31-33, 40, 41, 45, 46, 47, 50, 53-56, 58, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by LEONI (U. S. Patent No. 5,772,681).

Leoni describes a catheter having a knitted reinforcing member of nitinol between an inner liner and outer cover that is generally not expandable in the section adjacent to the balloon section (1:13-15, 2:48-3:20, 4:10-20, 5:28-29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 8, 9, 10, 11, 12, 15, 21, 28, 29, 30, 34, 35, 36, 37, 38, 39, 42, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-220225 or LEONI and further in view of ANDERSEN et al. (U. S. Patent No. 5,674, 276). JP 05-220225 or Leoni disclose the claimed invention except for using multifilaments with first and second materials of a metal and a polymer. Andersen teaches using multifilaments with first and second materials of a metal and a polymer to give desired characteristics to the knitted material for making tubular medical devices where the tube has a knitted member between an inner liner and outer cover (1:50 - 2:46, 4:32-43, 6:5-43, 8:2-7). The tubular device, disclosed by Anderson, is made of a knitted member that generally does not expand, but rather experiences plastic deformation to increase its dimensions (3:19-21). Andersen also teaches the use of radiopaque material to aid in visualizing the device internally. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Andersen in the invention of JP 05-220225 or Leoni in order to tailor the tubular device with different properties to achieve different functions (6:54-58). The

use of stainless steel and platinum in medical devices to make use of their notoriously well-known properties would be obvious to the ordinary artisan and Applicant has not stated that he has achieved any unexpected results different from these materials well-known properties and usage.

Claims 17, 22, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-220225 or LEONI as applied to claims 54, 1, and 58 respectively above, and further in view of JANG et al. (U. S. Patent No. 4,898,591). JP 05-220225 or LEONI disclose the claimed invention except for the materials of construction of the inner and outer liner and cover respectively. Jang teaches the use of polyethylene as an inner liner and outer cover of a reinforced catheter to provide desired mechanical properties. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Jang in the invention of JP 05-220225 or Leoni in order to achieve the desired flexibility, torsion and column rigidity for the catheter.

Allowable Subject Matter

Claims 51 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant states that Fig. 5, submitted 15 April 1999 shows a coil between an inner liner and outer cover. The examiner does not agree. Fig. 5 does not show a coil between the inner liner and outer cover, but rather a coil 216 alongside the inner liner 212.

Applicant argues that the prior art does not show a knitted layer, taking the position that the term “knitted” in the reference does not mean knitted. The Examiner does not find this argument convincing. The reference must be read in light of its plain meaning. The reference discloses the layer to be knitted, and must be read as such. Applicant’s arguments that knitted actually means braided or woven has no support. An attempt to devise some arrangement from the drawings is misplaced. The drawings do not attempt to show the details required to determine whether the layer is knitted, braided, or woven, and are not required to show such details. The reference describes the layer as knitted and any attempts to interpret the drawings to show otherwise is not convincing.

Applicant argues that Leoni does not describe an interlocking knitted layer because such a knitted layer would not have filaments which are moveable with respect to each other at crossover points. The examiner does not agree because knits of interconnecting or interlocking loops are free to move with respect to each other, the interlocking occurs when the loops are prevented from acting totally independently. That is, there is some point at which the movements of one filament relative to a second filament has an effect on the second filament. Interlocking does not mean that there is no movement between filaments. Applicant has not explicitly defined this term to mean other than its ordinary meaning.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

mjh
4 December 2003



**MICHAEL J. HAYES
PRIMARY EXAMINER**